UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
August 1, 2019

Menlo Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38356**	**45-3757789**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I. R. S. Employer Identification No.)**

200 Cardinal Way, 2nd Floor
Redwood City, California 94063
(Address of principal executive offices, including ZIP code)

(650) 486-1416
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MNLO	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On August 1, 2019, Menlo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2019. The press release is being furnished as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release dated August 1, 2019

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Menlo Therapeutics, Inc.

/s/ Kristine Ball

Date: August 1, 2019

By: Kristine Ball
Senior Vice President, Corporate Strategy and
Chief Financial Officer

Exhibit 99.1

Menlo Therapeutics Reports Second Quarter 2019 Financial Results and Provides Program Updates Including Accelerated Timeline for Upcoming Clinical Data

~Results from Serlopitant Phase 2 Clinical Trial for the Treatment of Chronic Pruritus of Unknown Origin Anticipated in Q1 2020~

~Results from Serlopitant Phase 3 Clinical Trials for the Treatment of Pruritus with Prurigo Nodularis Anticipated in H1 2020~

REDWOOD CITY, Calif., August 1, 2019 -- Menlo Therapeutics Inc. (Nasdaq: MNLO), a late-stage biopharmaceutical company focused on the development of serlopitant for the treatment of pruritus (itch), today announced financial results for the second quarter ended June 30, 2019 and provided an update on its clinical development programs.

"We are pleased with the progress in our prurigo nodularis (PN) Phase 3 clinical trials and the rapid enrollment in our chronic pruritus of unknown origin (CPUO) Phase 2 clinical trial," said Steve Basta, Menlo's Chief Executive Officer. "We believe the rapid enrollment of the CPUO trial reflects the large patient population and significant unmet need to manage pruritus in CPUO patients, for which there is currently no approved treatment."

Clinical Program Updates

Prurigo Nodularis

- Menlo is currently conducting two Phase 3 clinical trials (one in the U.S. and one in Europe) to evaluate serlopitant as a treatment for pruritus associated with PN. Each trial is targeted to enroll approximately 280 patients. There are currently 213 patients enrolled in the U.S. trial and 241 patients enrolled in the European trial. Menlo is on track as previously indicated to report top-line data from these PN Phase 3 trials in the first half of 2020.

- Menlo is also currently enrolling patients in a 52-week, multicenter, open-label safety study of serlopitant for the treatment of pruritus. The objective of this study is to provide long-term safety data for serlopitant in adults with pruritus, consistent with ICH and FDA guidelines, which recommend that drugs being developed for long-term treatment be evaluated for safety in at least 100 patients treated for 12 months and 300 patients treated for 6 months. Over 350 patients have been enrolled in this open-label study to date.

Chronic Pruritus of Unknown Origin

- Menlo is conducting a Phase 2 clinical trial in patients with chronic pruritus of unknown origin and expects to enroll approximately 200 patients in this trial. Menlo has enrolled 143 patients in this trial to date. Due to success accelerating enrollment in the CPUO trial, Menlo expects to report top-line data from this trial in the first quarter of 2020, earlier than previously indicated.

Psoriasis

- In December 2018, Menlo successfully completed a Phase 2 clinical trial in patients with pruritus associated with psoriasis which met the primary endpoint demonstrating a statistically significant improvement in pruritus in serlopitant-treated patients versus placebo. Menlo has chosen to defer the decision to start a Phase 3 clinical program in pruritus associated with psoriasis until 2020 in consideration of prudent resource prioritization and allocation management. Menlo plans to further clarify with the FDA the target population of patients for the proposed program, consider any learnings from its ongoing PN and CPUO trials once complete, and evaluate the opportunity

in psoriasis compared to potential alternative investments, such as accelerating the CPUO development program.

Financial Results

Second Quarter 2019 Financial Results

Menlo reported a net loss attributable to common stockholders of $16.5 million for the second quarter of 2019, compared to a net loss of $8.3 million for the same period in 2018.

Collaboration and license revenue was zero in the second quarter of 2019 compared to $10.1 million for the same period in 2018. The decrease in collaboration and license revenue was due to the termination of Menlo's collaboration agreement with JT Torii in June 2018.

Research and development expenses were $13.5 million in the second quarter of 2019, compared to $16.2 million for the same period in 2018. The decrease was primarily due to a May 2018 $3.0 million milestone payment to Merck resulting from the initiation of Menlo's Phase 3 clinical trials for pruritus associated with prurigo nodularis.

General and administrative expenses were $3.8 million in the second quarter of 2019, compared to $3.1 million for the same period in 2018. The increase was primarily due to an increase in personnel expenses as a result of an increase in Menlo's employee headcount and stock-based compensation expense and an increase in professional and insurance fees.

As of June 30, 2019, Menlo had $109.4 million in cash, cash equivalents and investments, compared to $136.3 million as of December 31, 2018. In the second quarter of 2019, Menlo issued 246,416 shares of its common stock pursuant to its at-the-market program at an average price of $7.84 per share and received aggregate net proceeds of $1.9 million after deducting sales agent fees.

Updated Operating Expense and Cash Runway Guidance

Menlo is lowering its operating expense guidance for the full year 2019 to a range of approximately $74.0 to $80.0 million, including stock-based compensation of approximately $5.0 to $6.0 million, from a range of $78.0 to $88.0 million. The decrease is primarily due to Menlo deferring the decision to start a Phase 3 clinical program in pruritus associated with psoriasis until 2020. Menlo expects that its current cash, cash equivalents and investments will enable the company to fund its anticipated operating expenses and capital expenditure requirements into the first quarter of 2021.

About Menlo Therapeutics

Menlo Therapeutics Inc. is a late-stage biopharmaceutical company focused on the development of serlopitant, a once-daily oral NK_1 receptor antagonist, for the treatment of pruritus. The company's clinical development program for serlopitant includes two ongoing Phase 3 clinical trials for the treatment of pruritus associated with prurigo nodularis, a Phase 3 ready clinical program for the treatment of pruritus associated with psoriasis, and an ongoing Phase 2 clinical trial for the treatment of chronic pruritus of unknown origin.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Menlo Therapeutics, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including, but not limited to, statements regarding the potential safety and efficacy of serlopitant for the treatment of various conditions, expectations with respect to the timing of enrollment and the anticipated announcement of results of its clinical trials for pruritus associated with prurigo nodularis and chronic pruritus of unknown origin, the timing of potential regulatory filings, the regulatory process and regulatory approvals, and expected cash needs and operating expenses in the second half of 2019. Such forward-looking statements involve substantial risk and uncertainties that could cause Menlo Therapeutics' development program for serlopitant, future financial results, achievements or performance to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks that the timing of results, enrollment or commencement of clinical trials may be delayed, the risk that subsequent trials are unsuccessful, despite prior successfully completed clinical trials or do not demonstrate efficacy of serlopitant in the studied indications, the risk of adverse safety events, risks that the costs of clinical trials will exceed expectations, risks resulting from the unpredictability of the regulatory process and regulatory developments in the United States and foreign countries, risks relating to ongoing securities class action litigation, and risks that Menlo Therapeutics will need to raise additional capital and will be unable to do so on favorable terms or at all. These factors, together with those that are described in greater detail in Menlo Therapeutics' Quarterly Report on Form 10-Q to filed on August 1, 2019, as well as any reports that it may file with the SEC in the future, may cause Menlo Therapeutics' actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. Menlo Therapeutics undertakes no obligation to update or revise any forward-looking statements.

- See attached financial tables –

Menlo Therapeutics Inc.
Condensed Statements of Operations
(In thousands, except share and per share data, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration and license revenue	$ -	$ 10,143	$ -	$ 10,640
Operating expenses:				
Research and development	13,457	16,226	29,380	27,246
General and administrative	3,759	3,090	7,504	5,787
Loss from operations	(17,216)	(9,173)	(36,884)	(22,393)
Interest income and other expense, net	739	826	1,534	1,388
Net loss	$ (16,477)	$ (8,347)	$ (35,350)	$ (21,005)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.69)	$ (0.36)	$ (1.50)	$ (1.04)
Weighted average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	23,893,580	22,872,196	23,591,554	20,242,341

Menlo Therapeutics Inc.
Condensed Balance Sheet Data
(In thousands)

	June 30, 2019	December 31, 2018 (1)
	(unaudited)	
Cash, cash equivalents and investments	$ 109,410	$ 136,250
Working capital	101,221	129,956
Total assets	114,384	139,928
Stockholders' equity	102,177	130,377

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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